

**UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO.
EASTERN DIVISION, AKRON**

JANE OLSZESKI
2989 Smith Kramer Street, NE
Hartville, OH 44632

Plaintiff,

VS

ETHICON WOMEN'S HEALTH
AND UROLOGY
c/o Statutory Agent, Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

and

GYNECARE
c/o Statutory Agent, Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

and

ETHICON, INC.
c/o Statutory Agent, Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

and

JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Defendants.

: CASE NO.:

: JUDGE:

: **ASSESSMENT OF DAMAGES
HEARING IS REQUIRED**

: **JURY TRIAL DEMANDED**

CIVIL ACTION COMPLAINT

Plaintiff, JANE OLSZESKI, by and through her attorneys and files this her Complaint against ETHICON WOMEN'S HEALTH AND UROLOGY, GYNECARE, ETHICON, INC., and JOHNSON & JOHNSON, Defendants, and alleges as follows:

PARTIES

1. Plaintiff JANE OLSZESKI, ("Plaintiff") is, and was at all relevant times, a resident of Hartville, Ohio.
2. Defendant ETHICON WOMEN'S HEALTH AND UROLOGY is a division of ETHICON, INC., a JOHNSON & JOHNSON company. ETHICON WOMEN'S HEALTH AND UROLOGY is corporation and citizen of the state of New Jersey, with its principal place of business located at 555 US-22, Somerville, New Jersey.
3. Defendant GYNECARE is a division of ETHICON, INC., a JOHNSON & JOHNSON company. GYNECARE is a corporation and citizen of the state of New Jersey, with its principal place of business located at 555 US-22, Somerville, New Jersey.
4. Defendant ETHICON, INC. is a wholly owned subsidiary of JOHNSON & JOHNSON. ETHICON, INC. is a corporation and citizen of the state of New Jersey, and its principal place of business is located at 555 US-22, Somerville, New Jersey.
5. Defendant JOHNSON & JOHNSON is a corporation and citizen of the state of New Jersey, and, according to its website, is the world's largest and most diverse medical device and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

JURISDICTION AND VENUE

6. This Court has personal jurisdiction over all Defendants pursuant to Ohio's 'long-arm' statute, R.C. 2307.382(A)(1), under which an Ohio court may exercise personal jurisdiction over a person who acts directly or by an agent, as to a cause of action arising from, among other things, the person's transacting any business in this state; contracting to supply services or goods in this state; causing tortious injury by an act or omission in this state; causing tortious injury in this state by an

act or omission outside this state if he regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this state. Defendants meet one or more or all of these conditions and transact business within the state of Ohio, regularly do or solicit business in the state, derive substantial revenue from goods used in the state, should reasonably expect their acts to have consequences in the state, and derive substantial revenue from interstate commerce within the State of Ohio, including Stark County and the northern district of Ohio, through their substantial and purposeful transactions of business there, including but not limited to their sales of the synthetic pelvic mesh products. On or about February 24, 2009, Plaintiff was implanted with Defendant's Pelvic Mesh Product—a surgical repair mesh packaged as the Gynecare TVT-Obturator—during a surgical procedure conducted by her surgeon, Melissa S. Vassas, D.O., at Aultman Hospital West in Canton, Ohio. Defendants have significant contacts with Stark County such that they are subject to personal jurisdiction within the State of Ohio.

7. This Court has diversity subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because it is a civil action in which the matter in controversy exceeds the sum or value of \$75,000, exclusive of interests and costs, and is between citizens of different States.

FACTUAL BACKGROUND

8. In or about October 2002, Defendants began to manufacture, market, and sell a product known as Gynemesh for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references herein to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

9. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress

urinary incontinence. Prolene Mesh was derived from Defendants' Prolene mesh hernia product which was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references herein to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft Mesh.

10. On or about January 1, 2005, without obtaining clearance from the United States Food and Drug Administration (FDA), Defendants began to market and sell a product known as the Prolift System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift System was and is offered as an anterior, posterior, or total repair system, and all references herein to the Prolift and/or Prolift System include by reference all variations thereof.

11. In or about May 2008, Defendants began to market and sell a product known as Prolift+M System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift+M System was and is offered as an anterior, posterior, or total repair system, and all references herein to the Prolift+M and/or Prolift+M System include by reference all variations thereof.

12. In or about March 2010, Defendants began to market and sell a product known as the Prosima System, for the treatment of medical conditions in the female pelvis—primarily pelvic organ prolapse. The Prosima was offered as an anterior, posterior, or total repair system, and all references to Prosima herein include by reference all variations thereof.

13. Defendants marketed and sold product known as TVT for the treatment of stress urinary incontinence in females. The TVT has been and is offered in multiple and significant variations including, but not limited to the TVT, TVT-Obturator (TVT-O), TVT Secure (TVT-S), TVT Exact and TVT Abbrevio. All references to TVT herein include by reference all variations thereof.

14. As stated above, the products known as Prolene Mesh, Gynemesh, Prolift, Proxima, Prolift+M, and TVT, as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendants' "Pelvic Mesh Products."

15. At all times relevant herein, Defendants designed, patented, manufactured, labeled, marketed, sold, and distributed Defendants' Pelvic Mesh Products, and did so knowingly, with the intent that the Pelvic Mesh Products would be surgically implanted in women.

16. On or about February 24, 2009, Plaintiff was implanted with Defendants' Pelvic Mesh Product—a surgical repair mesh packaged as the Gynecare TVT-Obturator—during a surgical procedure conducted by her surgeon, Melissa S. Vassas, D.O., at Aultman Hospital West in Canton, Ohio. The TVT-Obturator referenced herein is Defendants' "Pelvic Mesh Product." Plaintiff has been diagnosed with chronic pelvic pain, left lower abdominal/pelvic pain, levator spasms, complications of implanted vaginal mesh, groin pain, pudendal neuralgia, and recurrent incontinence. Plaintiff was informed by Dr. Cecile Unger, M.D. that the Ethicon, Inc. TVT-O required surgical revision as it had failed on April 9, 2019 and is a source of her above described symptoms and diagnoses. Plaintiff is pursuing treatment, including pelvic floor physical therapy, pudendal nerve block surgeries, and TVT-O revision surgery as recommended by Dr. Cecile Unger of The Cleveland Clinic.

17. Defendants' Pelvic Mesh Product was implanted in Plaintiff to treat her stress urinary incontinence, the use for which Defendants manufactured, marketed, and/or sold their Pelvic Mesh Product.

18. As a result of having the Pelvic Mesh Product implanted in her, Plaintiff has sustained permanent injuries including pain, suffering, mental anguish, physical impairment, and has

incurred economic damages including reasonable medical expenses and other expenses, and lost earning capacity, and will continue to experience and suffer those damages in the future.

19. At all relevant times, Defendants marketed their Pelvic Mesh Products (including the Pelvic Mesh Product) to the medical community, medical device manufacturers, patients, and consumers as safe, effective, and reliable medical devices that could be implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as being safer and more effective compared to other products and procedures for treatment of these and similar conditions.

20. Defendants marketed and sold their Pelvic Mesh Products (including the Pelvic Mesh Product) to medical device manufacturers, the medical community at large, and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies included, without limitation, direct-to-consumer advertising including aggressive marketing to healthcare providers at medical conferences, hospitals, and private offices and the provision of valuable consideration and benefits to healthcare providers. Defendants also utilized documents, brochures, websites, and/or telephone information lines in offering exaggerated and misleading expectations as to the safety and utility of the products.

21. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, Defendants' Pelvic Mesh Products (including the Pelvic Mesh Product) have high failure rates and high injury and complication rates; fail to perform as intended; require frequent and often debilitating re-operations; and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff.

22. Upon information and belief, Defendants have consistently underreported and withheld information about the propensity of the Pelvic Mesh Products (including the Pelvic Mesh Product)

to fail and to cause injury and complications, have misrepresented the efficacy and safety of their Pelvic Mesh Products (including the Pelvic Mesh Product) through various means and media, and have actively and intentionally misled the FDA, the medical community, patients, and the public at large about those products.

23. Defendants have known at all times and have had reason to know that their Pelvic Mesh Products (including the Pelvic Mesh Product) were and are causing numerous patients severe injuries and complications including those suffered by Plaintiff; and that their disclosures to the FDA were and are incomplete and misleading. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, healthcare providers, and patients. As a result, Defendants actively and intentionally misled and continue to mislead the public, including the medical community, healthcare providers, and patients, including Plaintiff and her doctor, into believing that their Pelvic Mesh Products were and are safe and effective, which led to the prescribing and implantation of the Pelvic Mesh Product in Plaintiff.

24. Defendants individually and/or jointly failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products (including the Pelvic Mesh Product).

25. Knowing the significant risk that the Pelvic Mesh Products (including the Pelvic Mesh Product) would fail and/or imperil the health and welfare of the women in which they were implanted, Defendants failed to properly design the Pelvic Mesh Products or to establish a safe, effective procedure for the removal of the Pelvic Mesh Products, rendering it impossible to safely or easily remove the Pelvic Mesh Products leading to foreseeable injuries to patients including Plaintiff.

26. Feasible and suitable alternative designs and products, as compared to Defendants' Pelvic Mesh Products (including the Pelvic Mesh Product) as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and other similar conditions, have existed at all times relevant.

27. The Pelvic Mesh Products (including the Pelvic Mesh Product) were at all times utilized and implanted in a manner foreseeable to Defendants including the implantation of Plaintiff's Pelvic Mesh Product.

28. Defendants have provided incomplete, insufficient, and misleading training and information to physicians in order to increase the number of physicians utilizing the Pelvic Mesh Products (including the Pelvic Mesh Product), and thus increase the sales of the Pelvic Mesh Products. This has led to the dissemination of inadequate and misleading information to doctors and patients, including Plaintiff and her physician.

29. The Pelvic Mesh Product implanted into Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by Defendants.

30. The injuries, conditions, and complications suffered by Plaintiff and others due to the Pelvic Mesh Product include without limitation dyspareunia, spastic pelvic floor syndrome, pudendal neuralgia, obturator neuralgia, pelvic pain, groin pain, vaginal pain, inner thigh pain, depression, and recurrent urinary incontinence.

31. Despite knowledge of these catastrophic injuries, conditions, and complications caused by the Pelvic Mesh Products (including the Pelvic Mesh Product), Defendants manufactured, marketed, and sold the Pelvic Mesh Products while failing to adequately warn, label, instruct, and

disseminate information with regard to the Pelvic Mesh Products, both prior to and after the marketing and sale of the Pelvic Mesh Products.

32. On or about January 3, 2012, the FDA ordered Defendants to conduct randomized, controlled clinical testing of the Pelvic Mesh Products or be ordered to cease their manufacture, marketing, and sale.

33. On or about June 5, 2012, Defendants announced that they were withdrawing some and/or all of the Pelvic Mesh Products, from the market and, as a result, would not be conducting the randomized, controlled clinical testing ordered by the FDA.

34. As of the date of the filing of this Complaint, Defendants have not begun or completed any of the randomized, controlled clinical testing ordered by the FDA.

COUNT I – STRICT LIABILITY – DEFECTIVE MANUFACTURE AND DESIGN

35. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

36. Defendants' Pelvic Mesh Products were, in certain instances, defectively and improperly manufactured, rendering the Pelvic Mesh Products deficient and unreasonably dangerous and hazardous to Plaintiff.

37. Defendants' Pelvic Mesh Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their healthcare providers.

38. The Pelvic Mesh Products create risks to patients' health and safety that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products.

39. The Pelvic Mesh Product is not reasonably safe and is so likely to be harmful to users that a reasonable person with actual knowledge of its potential for producing injury would conclude that it should not have been marketed.

40. The Pelvic Mesh Product's characteristics render it dangerous beyond the degree that would be contemplated by an ordinary person, doctor, or patient with the ordinary knowledge common to the community.

41. Defendants have intentionally and recklessly designed, manufactured, marketed, labeled, sold, and distributed the Pelvic Mesh Product with wanton and willful disregard for the rights and health of Plaintiff, and with malice, placing their economic interests above the health and safety of Plaintiff.

42. As a direct and proximate result of Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Product, Plaintiff was injured catastrophically, sustaining severe and permanent pain, suffering, mental anguish, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

COUNT II – STRICT LIABILITY – FAILURE TO WARN

43. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

44. Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the proper candidates for, and the safest and most effective methods of, implantation and use of Defendants' Pelvic Mesh Product.

45. Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the risks and potential complications of Defendants' Pelvic Mesh Product, given Plaintiff's conditions and need for information.

46. Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of the Pelvic Mesh Product, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Product.

47. Due to the improper and inadequate warnings, Defendants' Pelvic Mesh Product is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and does not meet or perform to the expectations of patients and their healthcare providers.

48. Due to the improper and inadequate warnings, the Pelvic Mesh Product creates health and safety risks to patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Product.

49. Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of Defendants' Pelvic Mesh Product, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for Plaintiff's rights and health.

50. As a proximate result of Defendants' failure to warn Plaintiff and her medical professionals of the defective design, manufacture, labeling, and marketing of the Pelvic Mesh Product, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, mental anguish, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

COUNT III – NEGLIGENCE

51. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

52. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Pelvic Mesh Product, as well as in the recruitment and training of physicians to implant the Pelvic Mesh Products.

53. Defendants breached their duty of care to Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the Pelvic Mesh Product.

54. Defendants further breached their duty of care to Plaintiff by failing to conduct post-market vigilance or surveillance, by failing to monitor or act on findings in the scientific and medical literature, and by failing to monitor or investigate and evaluate reports in the FDA adverse event databases for their potential significance for Defendants' Pelvic Mesh Product.

55. As a proximate result of Defendants' negligent design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Product, Plaintiff has been injured catastrophically, sustained severe and permanent pain, suffering, mental anguish, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

COUNT IV – COMMON LAW FRAUD

56. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

57. Defendants falsely and fraudulently represented and continue to represent to the medical and healthcare community, Plaintiff, the FDA, and the public that the Pelvic Mesh Products had been tested and were found to be safe and effective.

58. The representations made by Defendants were, in fact, false. When Defendants made their representations, Defendants knew and/or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Pelvic Mesh Product.

59. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Product for use as a means of treatment for stress urinary incontinence, all of which evidenced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

60. In representations to Plaintiff and/or to Plaintiff's healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

- a. That Defendants' Pelvic Mesh Product was not as safe as other products and procedures available to treat incontinence;
- b. That the risk of adverse events with Defendants' Pelvic Mesh Product was higher than with other products and procedures available to treat incontinence;
- c. That Defendants' Pelvic Mesh Product was not adequately tested;
- d. That the limited clinical testing revealed Defendants' Pelvic Mesh Product had a higher risk of adverse effects in addition to and above and beyond those associated with other products and procedures available to treat incontinence;

- e. That Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers, and buried and/or misrepresented those findings;
- f. That Defendants deliberately chose to forego studies that might reveal the true rate of adverse events or otherwise necessitate the need to reveal information as to adverse events to Plaintiff, the medical community, or the regulatory authorities;
- g. That Defendants were aware of dangers in Defendants' Pelvic Mesh Product in addition to and above and beyond those associated with other products and procedures available to treat incontinence;
- h. That Defendants' Pelvic Mesh Product was defective and that it caused dangerous and adverse effects, including but not limited to higher incidence of erosion and failure at a much more significant rate than other products and procedures available to treat incontinence;
- i. That patients needed to be monitored more regularly than usual while using Defendants' Pelvic Mesh Product and that, in the event the product needed to be removed, the procedures to remove it had a very high failure rate and/or had to be performed repeatedly;
- j. That Defendants' Pelvic Mesh Product was manufactured negligently;
- k. That Defendants' Pelvic Mesh Product was manufactured defectively;
- l. That Defendants' Pelvic Mesh Product was designed negligently; and
- m. That Defendants' Pelvic Mesh Product was designed defectively.

61. Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of Defendants' Pelvic Mesh Product, including but not limited to the heightened risks of erosion, failure, and permanent injury.

62. Defendants had sole access to material facts concerning the defective nature of the products, their propensity to cause serious and dangerous side effects, and hence to cause dangerous injuries and damage to persons who used Defendants' Pelvic Mesh Product.

63. Defendants' concealment and omissions of material facts concerning the safety of the Pelvic Mesh Product were made purposefully, willfully, wantonly, and/or recklessly to mislead and to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Pelvic Mesh Product, and/or to mislead Plaintiff into reliance and to cause Plaintiff to use Defendants' Pelvic Mesh Product.

64. At the time these representations were made by Defendants, and at the time Plaintiff used the Pelvic Mesh Product, Plaintiff was unaware of the falsehood of these representations and reasonably believed them to be true.

65. Defendants knew and had reason to know that Defendants' Pelvic Mesh Product could and would cause severe and grievous personal injury to the users of the Product and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

66. In reliance upon these false representations, Plaintiff was induced to and did use the Pelvic Mesh Product, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions and

that these included material omissions of facts surrounding the use of Defendants' Pelvic Mesh Product, as described in detail herein.

67. Plaintiff and her physicians reasonably relied on information propagated by Defendants which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of Defendants' Pelvic Mesh Product.

68. Having knowledge based upon Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including without limitation assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians that Defendants' Pelvic Mesh Product was safe and effective for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe as or safer than other products and/or procedures then available and on the market. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed, and suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

69. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers, and the FDA.

70. The information distributed by Defendants to the public, the medical community, the FDA, and Plaintiff included without limitation websites, product brochures and pamphlets, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media containing material representations. This information was false and misleading and contained omissions and concealment of the truth about the dangers of the use of Defendants' Pelvic Mesh Product.

71. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of Defendants' Pelvic Mesh Product, specifically that the Pelvic Mesh Product did not have dangerous and/or serious adverse health and safety concerns and that Defendants' Pelvic Mesh Product was as safe as or safer than other means of treating stress urinary incontinence.

72. Defendants intentionally failed to inform the public, including Plaintiff, of the severity and frequency of complications from the Pelvic Mesh Product, the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

73. Instead, Defendants chose to over-promote the purported safety, efficacy, and benefits of Defendants' Pelvic Mesh Product.

74. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Pelvic Mesh Product; and to induce Plaintiff, the public, and the medical community to request, recommend, prescribe, dispense, purchase, implant, use, and continue to use Defendants' Pelvic Mesh Product.

75. Defendants made claims and representations in their documents submitted to the FDA and their reports to the public and to healthcare professionals and in advertisements that Defendants' Pelvic Mesh Product had innovative beneficial properties and did not present serious health risks.

76. These representations, and others made by Defendants, were false when made, were made with the pretense of actual knowledge when such knowledge did not actually exist, and/or were made recklessly and without regard to the true facts.

77. These representations and others were made by Defendants with the intention of deceiving and defrauding Plaintiff and Plaintiff's healthcare professionals; were made to induce Plaintiff and her healthcare professionals to rely on these misrepresentations; caused Plaintiff to purchase, rely on, request, and use Defendants' Pelvic Mesh Product; caused her healthcare professionals to rely on Defendants' misrepresentations, dispense, recommend, prescribe and/or implant Defendants' Pelvic Mesh Product in Plaintiff.

78. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of Defendants' Pelvic Mesh Product to the public at large for the purpose of influencing the sales of products known to be dangerous and defective and/or not as safe as other alternatives.

79. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts, and made false representations for the purpose of deceiving and lulling Plaintiff, as well as her healthcare professionals, into a false sense of security so that Plaintiff and her healthcare providers would rely on Defendants' representations, that Plaintiff would request and purchase Defendants' Pelvic Mesh Product, and that her healthcare providers would recommend, dispense, prescribe, and implant Defendants' Pelvic Mesh Product in Plaintiff.

80. Defendants utilized direct-to-consumer advertising, including product brochures and pamphlets, to market, promote, and advertise Defendants' Pelvic Mesh Product.

81. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of Defendants' Pelvic Mesh Product. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants,

nor could Plaintiff have discovered with reasonable diligence the true facts or Defendants' misrepresentations.

82. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Defendants' Pelvic Mesh Products, Plaintiff would not have purchased, used, or relied on Defendants' Pelvic Mesh Products.

83. Defendants' wrongful conduct constitutes fraud and deceit and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

84. As a proximate result of Defendants' conduct, Plaintiff has been injured catastrophically, sustaining severe and permanent pain, suffering, mental anguish, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

COUNT V – FRAUDULENT CONCEALMENT

85. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

86. Throughout the relevant time period, Defendants knew that their Pelvic Mesh Product was defective and unreasonably unsafe for its intended purpose.

87. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiff, her physicians, and the medical community that their Pelvic Mesh Product was defective, unsafe, unfit for the purposes intended, and not of merchantable quality.

88. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Pelvic Mesh Product because Defendants were in a superior position to know the true quality, safety, and efficacy of Defendants' Pelvic Mesh Product.

89. Defendants breached that duty by misrepresenting material facts that a reasonable person would have considered to be important in deciding whether to purchase and/or use Defendants' Pelvic Mesh Product:

- a. Defendants knowingly made false claims about the safety and quality of Defendants' Pelvic Mesh Product in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and
- b. Defendants fraudulently and affirmatively concealed the defective nature of Defendants' Pelvic Mesh Product from Plaintiff and her healthcare providers.

90. Defendants intentionally concealed and/or failed to disclose the true, defective nature of the Pelvic Mesh Product so that Plaintiff would request and purchase Defendants' Pelvic Mesh Product, and so that her healthcare providers would dispense, prescribe, and recommend Defendants' Pelvic Mesh Product, and Plaintiff justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of Defendants' Pelvic Mesh Product.

91. By concealment or other action, Defendants intentionally prevented Plaintiff and Plaintiff's physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of Defendants' Pelvic Mesh Product. Defendants are subject to the same liability to Plaintiff for her pecuniary losses, as though Defendants had affirmatively denied the existence of such material information regarding the Pelvic Mesh Product's lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiff was thus prevented from seeking or discovering the truth. Defendants are therefore liable for fraudulent concealment under all applicable law, including, inter alia, Restatement of Torts § 402A.

92. As a proximate result of Defendants' conduct, Plaintiff has been injured catastrophically, sustaining severe and permanent pain, suffering, mental anguish, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

COUNT VI – CONSTRUCTIVE FRAUD

93. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

94. Defendants were in a unique position of knowledge concerning the quality, safety and efficacy of Defendants' Pelvic Mesh Product, with such knowledge not possessed by Plaintiff or her physicians, and Defendants thereby hold a position of superiority over Plaintiff.

95. Despite their unique knowledge regarding the defective nature of Defendants' Pelvic Mesh Product, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiff, the medical community, and/or the FDA concerning the severity of risks and the dangers inherent in the intended use of Defendants' Pelvic Mesh Product as compared to other products and forms of treatment.

96. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that Defendants' Pelvic Mesh Product had a higher risk of adverse effects in addition to and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the Pelvic Mesh Product.

97. Upon information and belief, Defendants' misrepresentations were designed to induce physicians and Plaintiff to prescribe, dispense, recommend and/or purchase Defendants' Pelvic Mesh Product. Plaintiff, her healthcare providers, and the medical community reasonably relied on Defendants' representations.

98. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and engaged in constructive fraud in their relationship with Plaintiff. Plaintiff reasonably relied on Defendants' representations.

99. As a proximate result of Defendants' conduct, Plaintiff has been injured catastrophically, sustaining severe and permanent pain, suffering, mental anguish, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

COUNT VII – NEGLIGENT MISREPRESENTATION

100. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

101. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, and to Plaintiff, the test results for their Pelvic Mesh Product. Defendants falsely represented that the Pelvic Mesh Product had been tested and found to be safe and effective for the treatment of incontinence and prolapse.

102. Defendants failed to exercise ordinary care in their representations concerning the Pelvic Mesh Product while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently omitted from their representations the fact that the Pelvic Mesh Product had a high risk of unreasonable, dangerous, and adverse side effects.

103. Defendants breached their duty in representing to Plaintiff, her physicians, and the healthcare community that Defendants' Pelvic Mesh Product has no serious side effects other than those effects associated with older generations of similar products and/or procedures.

104. As a foreseeable, direct, and proximate result of the negligent misrepresentations by Defendants as set forth herein, Defendants knew, and had reason to know, that the Pelvic Mesh Product had been insufficiently tested, or had not been tested at all; lacked adequate and accurate warnings; and created a higher than acceptable risk, and/or higher than reported and represented risk of adverse side effects, including erosion; pain and suffering; the difficulties in surgically removing the product; and the likelihood of other severe personal injuries, which are permanent and lasting in nature, including those suffered by Plaintiff.

105. As a proximate result of Defendants' conduct, Plaintiff has been injured catastrophically, sustaining severe and permanent pain, suffering, mental anguish, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

COUNT VIII – NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

106. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

107. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed, and sold Defendants' Pelvic Mesh Product to Plaintiff; carelessly and negligently concealed the harmful effects of Defendants' Pelvic Mesh Product from Plaintiff; and carelessly and negligently misrepresented the quality, safety, and efficacy of the Pelvic Mesh Product.

108. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the Pelvic Mesh Product sold and distributed by Defendants.

109. As a proximate result of Defendants' conduct, Plaintiff has been injured catastrophically, sustaining severe and permanent pain, suffering, mental anguish, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

COUNT IX - BREACH OF EXPRESS WARRANTY

110. Plaintiff realleges and incorporates each and every allegation of this Complaint as if each were set forth fully and completely herein.

111. At all relevant times, Defendants manufactured, distributed, advertised, promoted, and sold the Pelvic Mesh Product.

112. At all relevant times, Defendants intended that their Pelvic Mesh Product be used in the manner that Plaintiff in fact used it, and Defendants expressly warranted that the product was safe and fit for use by consumers for the purposes of treating stress urinary incontinence and that it was of merchantable quality, that its side effects were minimal and comparable to those of other surgical treatment options, and that it was adequately tested and fit for its intended use.

113. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the Pelvic Mesh Product, which is to say that Plaintiff was a foreseeable user of Defendants' Pelvic Mesh Product.

114. Plaintiff and/or her implanting physicians were at all relevant times in privity with Defendants.

115. Defendants' Pelvic Mesh Product was expected to reach and did in fact reach consumers, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

116. Defendants breached various express warranties with respect to the Pelvic Mesh Product, including the following:

- a. Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Defendants' Pelvic Mesh Product was safe; and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Product;
- b. Defendants represented to Plaintiff and her physicians and healthcare providers that Defendants' Pelvic Mesh Product was as safe as and/or safer than other alternative procedures and devices, and fraudulently concealed information demonstrating that the Pelvic Mesh Product was not as safe as or safer than alternatives available on the market; and,
- c. Defendants represented to Plaintiff and her physicians and healthcare providers that Defendants' Pelvic Mesh Product was more efficacious than alternative products, procedures and/or medications; and fraudulently concealed information regarding the true efficacy of Defendants' Pelvic Mesh Product.

117. In reasonable reliance upon Defendants' express warranties, Plaintiff was implanted with Defendants' Pelvic Mesh Product as prescribed and directed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

118. At the time of making such express warranties, Defendants knew or should have known that Defendants' Pelvic Mesh Product did not conform to these express representations because Defendants' Pelvic Mesh Product was not safe and could cause numerous serious complications,

many of which Defendants did not accurately warn about, thus making Defendants' Pelvic Mesh Product unreasonably unsafe for its intended purpose.

119. Members of the medical community, including Plaintiff's physicians and other healthcare professionals, reasonably relied on Defendants' representations and warranties in connection with the recommendation, description, dispensing, and use of Defendants' Pelvic Mesh Product.

120. Defendants knowingly, intentionally, and recklessly breached their express warranties to Plaintiff in that Defendants knew that their Pelvic Mesh Product was not of merchantable quality, was neither safe nor fit for its intended uses, nor had it been adequately tested.

121. Defendants' breaches constituted violations of common law and of Ohio statutory principles set forth in Ohio Revised Code §2307.71 through 2307.80, with specific reference to the definition of "representation" in Revised Code §2307.71 (A)(14).

122. As a proximate result of Defendants' conduct, Plaintiff has been injured catastrophically, sustaining severe and permanent pain, suffering, mental anguish, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

COUNT X - BREACH OF IMPLIED WARRANTY

123. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

124. At all relevant times, Defendants manufactured, distributed, advertised, promoted, and sold Defendants' Pelvic Mesh Product.

125. At all relevant times, Defendants intended that Defendants' Pelvic Mesh Product be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them. Defendants impliedly warranted each product to be of merchantable quality, safe

and fit for such use, and adequately tested. In fact, the Pelvic Mesh Product was not of merchantable quality, was not safe and fit for its intended use, and had not been adequately tested.

126. Defendants were aware that consumers, including Plaintiff and/or Plaintiff's physicians, would implant or agree to have implanted Defendants' Pelvic Mesh Product in the manner directed by the instructions for use. In short, Plaintiff was a foreseeable user of Defendants' Pelvic Mesh Products.

127. At all relevant times, Plaintiff and/or her physicians were in privity with Defendants.

128. Defendants' Pelvic Mesh Product was expected to reach and did in fact reach consumers, including Plaintiff and/or Plaintiff's physicians, without substantial change in the condition in which the Pelvic Mesh Product was manufactured and sold by Defendants.

129. Defendants breached various implied warranties with respect to Defendants' Pelvic Mesh Product, including the following particulars:

- a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Defendants' Pelvic Mesh Product was safe; and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Product;
- b. Defendants represented that Defendants' Pelvic Mesh Product was safe and/or safer than alternative devices or procedures, and fraudulently concealed information demonstrating that Defendants' Pelvic Mesh Product was not as safe as or safer than alternatives available on the market; and

- c. Defendants represented that Defendants' Pelvic Mesh Product was more efficacious than alternative medications, devices, and procedures; and fraudulently concealed information regarding the true efficacy of the Pelvic Mesh Product.

130. In reasonable reliance on Defendants' implied warranties, Plaintiff used the Pelvic Mesh Product as prescribed and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

131. In that the Pelvic Mesh Product was not of merchantable quality, was not minimally safe, was not reasonably fit for its intended use, and had not been adequately tested, Defendants breached their implied warranties to Plaintiff in violation of common law principles as well as Ohio Revised Code chapter 1302.

132. As a proximate result of Defendants' conduct, Plaintiff has been injured catastrophically, sustaining severe and permanent pain, suffering, mental anguish, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

COUNT XI - UNJUST ENRICHMENT

133. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

134. Defendants are and at all times were the manufacturers, sellers, and/or suppliers of Defendants' Pelvic Mesh Product.

135. Plaintiff paid for Defendants' Pelvic Mesh Product for the purpose of treatment of stress urinary incontinence.

136. Defendants have accepted payment by Plaintiff for the purchase of Defendants' Pelvic Mesh Product.

137. Plaintiff has not received the safe and effective medical device for which she paid.

138. It would be inequitable for Defendants to keep this money if Plaintiff did not in fact receive a safe and effective medical device.

COUNT XII – GROSS NEGLIGENCE

139. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

140. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law allows the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards, (1) was specifically intended to cause substantial injury to Plaintiff; (2) when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, that Defendants were actually, subjectively aware, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or (3) otherwise included a material representation that was false, despite Defendants' knowledge that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation was acted on by Plaintiff.

141. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

142. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

143. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the

injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct while deterring other manufacturers from engaging in such misconduct in the future.

COUNT XIII - PUNITIVE DAMAGES

144. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

145. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of Plaintiff, the public, and others, for which the law allows the imposition of punitive damages. , in that Defendants' conduct, including the failure to comply with applicable federal standards, (1) was specifically calculated to cause substantial injury to Plaintiff; (2) when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk on the part of Plaintiff, considering the probability and magnitude of the potential harm to Plaintiff and others, of which Defendants were actually, subjectively aware, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or (3) otherwise included a material representation that was false, despite Defendants' knowledge that it was false or made with reckless disregard as to its truth and as a positive assertion, with the intent that the representation was acted on by Plaintiff.

146. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

147. Defendants sold their Pelvic Mesh Products to Plaintiff's healthcare providers and other healthcare providers throughout the United States without doing adequate testing to ensure that the Pelvic Mesh Products were reasonably safe for implantation in the female pelvic area.

148. Defendants sold the Pelvic Mesh Products to Plaintiff's healthcare providers and other healthcare providers throughout the United States in spite of Defendants' knowledge that their Pelvic Mesh Products can shrink, disintegrate, degrade inside the body, and/or cause the other problems heretofore set forth in this Complaint, thereby causing the severe and debilitating injuries suffered by Plaintiff.

149. At all relevant times, Defendants knew or should have known that their Pelvic Mesh Product was inherently dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, and remedial surgeries and treatments necessary to address the conditions proximately arising from the use of the Pelvic Mesh Product, as well as other severe and personal injuries which are permanent and lasting in nature.

150. At all relevant times, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Defendants' Pelvic Mesh Product.

151. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of Defendants' Pelvic Mesh Product.

152. At all relevant times, Defendants knew and intentionally and/or recklessly disregarded the fact that Defendants' Pelvic Mesh Product cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods products and/or procedures and/or treatment.

153. At all relevant times, Defendants knew and intentionally and/or recklessly disregarded the fact that Defendants' Pelvic Mesh Product cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise healthcare providers and the public of the same.

154. At all relevant times, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the true and accurate risk of injuries and complications caused by Defendants' Pelvic Mesh Product.

155. Notwithstanding the foregoing, Defendants continue to aggressively market Defendants' Pelvic Mesh Product to consumers without disclosing the true risk of side effects and complications.

156. Defendants knew of their Pelvic Mesh Product's defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell Defendants' Pelvic Mesh Product so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiff, in conscious and/or reckless disregard of 'the foreseeable harm caused by Defendants' Pelvic Mesh Product.

157. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of Defendants' Pelvic Mesh Product in order to ensure continued and increased sales.

158. Defendants' intentional, reckless, and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using Defendants' Pelvic Mesh Product against their benefits.

159. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services and has incurred medical, healthcare, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care and/or hospital care and medical services.

160. Defendants have engaged in conduct entitling Plaintiff to an award of punitive damages.

161. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

DISCOVERY RULE AND TOLLING

162. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

163. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

164. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, .and the tortious nature of the wrongdoing that caused the injury.

165. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

166. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and her healthcare providers of the true risks associated with the Product.

167. As a result of Defendants' fraudulent concealment, Plaintiff and her healthcare providers were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Defendants.

WHEREFORE, Plaintiff demands judgment against each of the Defendants, jointly and severally, as follows:

1. On Count I (Strict Liability – Defective Manufacture and Design), compensatory and punitive damages in an amount in excess of \$75,000.00;
2. On Count II Strict Liability – Failure to Warn), compensatory and punitive damages in an amount in excess of \$75,000.00;
3. On Count III (Negligence), compensatory damages in an amount in excess of \$75,000.00;
4. On Count IV (Common Law Fraud), compensatory and punitive damages in an amount in excess of \$75,000.00;
5. On Count V (Fraudulent Concealment), compensatory and punitive damages in an amount in excess of \$75,000.00;
6. On Count VI (Constructive Fraud), compensatory and punitive damages in an amount in excess of \$75,000.00;
7. On Count VII (Negligent Misrepresentation), compensatory damages in an amount in excess of \$75,000.00;
8. On Count VIII (Negligent Infliction of Emotional Distress), compensatory damages in an amount in excess of \$75,000.00;
9. On Count IX (Breach of Express Warranty), compensatory and punitive damages

in an amount in excess of \$75,000.00;

10. On Count X (Breach of Implied Warranty), compensatory and punitive damages in an amount in excess of \$75,000.00;
11. On Count XI (Unjust Enrichment), compensatory damages in an amount to be proved at trial, consisting of all costs and expenses incurred in the purchase and implantation of the Pelvic Mesh Product marketed by Defendants;
12. On Count XII (Gross Negligence), compensatory and punitive damages in an amount in excess of \$75,000.00;
13. On Count XIII (Punitive Damages) where applicable and as set forth above on other counts where specified;
14. Costs, attorney fees, and such other and further relief as the Court deems just and proper.

Respectfully submitted,

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JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable as of right.

/s/ James W. Slater

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ATTORNEYS FOR PLAINTIFF